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Acupuncture and Pain: A Critical Analysis of Current Research

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ACUPUNCTURE AND PAIN: A CRITICAL ANALYSIS OF CURRENT RESEARCH

by

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Bachelor of Science in Physical Therapy
University of North Dakota, 1996

An Independent Study

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

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in partial fulfillment of the requirements

for the degree of

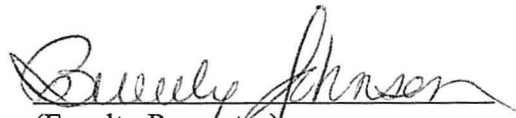
Master of Physical Therapy


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1997



This Independent Study, submitted by Ryan K. Kuwahara in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.


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ABSTRACT

Acupuncture as a treatment for pain relief has recently gained popularity in the United States despite the lack of substantial clinical proof of its analgesic effect. In the recent past there have been several reviews of the clinical studies on acupuncture's analgesic efficacy, all of which have demanded that future studies have more appropriate outcome measures, better design, and have proper credibility assessment. The present study critically analyzed the published literature over the past decade to see if the latest acupuncture studies provide a more definitive answer regarding acupuncture's efficacy. Analysis revealed that recent studies do not provide any more proof for or against acupuncture analgesia. The author suggests that the analgesic effect of acupuncture may indeed exist but may be so minimal as not to produce scientifically significant results in its favor. More high quality studies are required before a definitive conclusion can be determined.

CHAPTER 1

INTRODUCTION

Acupuncture, which originated in China over 3,000 years ago, has been one of the most controversial forms of non-pharmacological pain control in contemporary western medicine. The term acupuncture is used to describe a vast number of techniques, ranging from acupressure to laser acupuncture and includes a wide range of uses. While acupuncture has been widely used in Asia for centuries to treat nearly every type of disease or disorder, from asthma to addiction to nicotine, western science has been most concerned with acupuncture's pain-relieving qualities, and this is where most of the published literature has concentrated its efforts. Gains have been made in eliciting the physiological bases through which acupuncture achieves pain relief by the use of animal studies. In addition, acupuncture's use throughout Europe has gradually become accepted over the past century as a complement to conventional treatment in pain clinics and in general practice.¹ Today an estimated one million practitioners outside of China practice acupuncture for chronic pain, including over 300,000 physicians.² In 1987 there were an estimated 1000 physicians in the United Kingdom (UK) who practiced acupuncture.³ One recent study found that in German pain clinics, over 90% of the physicians used acupuncture.²

While the scientific establishment in the United States has historically been skeptical of "alternative" forms of medicine, acupuncture has recently grown in

acceptance among the general population as alternative to conventional pain relief treatment. As a result, the Food and Drug Administration is currently looking into its 1976 ruling on acupuncture which designated it an “experimental” procedure and is considering recognizing it as a legitimate medical procedure.²

With the chronic pain patient being a major player in physical therapy outpatient clinics, acupuncture as a pain relieving modality is of keen interest to the physical therapy (PT) profession. Within the profession acupuncture has increased its role within the past several years, with Europeans being at the forefront of this movement. In Canada, Sweden, Norway, South Africa, Australia, New Zealand, Japan and the UK, acupuncture is commonly used by physical therapists primarily to treat chronic painful conditions.¹ The holistic nature of acupuncture may be a reason why it has caught on so dramatically in the PT profession.¹ Furthermore, physical therapists have traditionally used modalities that appear to produce functional results, despite their lack of a fundamental research basis.¹

The growing interest in acupuncture in Europe as well as the United States and the evolution of healthcare in this nation have resulted in a demand for clinical scientific proof of acupuncture analgesia. There have been numerous clinical studies of acupuncture over the years showing modest promise of acupuncture analgesia, but the consensus is that in general these studies have been of poor design with various sources of potential bias.

This paper will be a brief overview of the holistic basis behind traditional Chinese acupuncture, the proposed biophysiological theories of acupuncture analgesia, the variety of techniques and methods used for acupuncture analgesia, and the methodological

problems plaguing past clinical studies of acupuncture analgesia. Finally, this paper will review the published clinical trials of the past decade to see if current research has resulted in a more definitive conclusion regarding acupuncture's role in pain relief.

CHAPTER 2

OVERVIEW OF TRADITIONAL CHINESE MEDICINE

The practice of acupuncture is based on the beliefs of traditional Chinese medicine (TCM). While written history of TCM dates back as far as 3000 years, the practice of acupuncture is believed to have originated even before this time.⁴

TCM is a holistic approach based on the concept of providing proper stimuli to return the body to its balanced state of health. The opposing forces of *Yin* (negative), and *Yang* (positive) govern the universe. In addition, yin and yang affect the human body as a whole as well as at every level, down to even the cellular structure,² and yin and yang energies form the basis for illness and health. The manifestation of the interaction between the opposing forces of Yin and Yang is *qi* (chi), the cosmic vital energy which is omnipresent in nature.

Qi governs all living organs and life functions through its movement and action. This vital energy flows within the body along a system of “channels” or “meridians”. The channels interact with and provide links between the inner “organs” through which qi may flow. The term “organ” in TCM refers not to the anatomical structure as defined by western medicine, but refers more to functions of organ systems. For example, the organ of the lung in TCM would include all functions and organs of the respiratory system, including olfactory function.²

There are 11 organs recognized by TCM, and these are associated with 12 main channels. The paths of the channels can be mapped on the surface of the body. Certain specific points near the surface of the skin identified as acupuncture points can give access to its respective channel. There are a total of 361 classic acupuncture points, and all are situated on a system of 14 channels. These 14 channels are comprised of the 12 main channels plus two subsidiary, or “extraordinary” channels.²

The balance of qi throughout its system of channels as well as the overall energy level is essential to determining the health and well-being of the individual. According to TCM, most illnesses and dysfunctions can be linked to the improper flow of qi, whether it be an excess or deficiency of qi in the organ systems or channels, or a blockage or stagnation of the vital energy.² Deficient vital energy would result in inadequate functioning at the appropriate organ system, whereas excess qi would result in excessive functioning.²

The diagnosis process involved in TCM is a difficult concept to understand for those schooled in Western medicine. However, if one keeps in mind that the TCM principles were developed at a time when there was no knowledge of physiology and when dissection of the human body was forbidden, the strong metaphysical, numerological and astrological concepts involved in TCM should not be surprising. The ancient theories and concepts of TCM have survived through centuries and even today are practiced virtually unchanged by some practitioners. Diagnosis in TCM involves analysis of the patient’s symptoms and signs to find “disturbance patterns” indicating disharmony of qi in the channels or organ systems.² It is critical that the assessment include a detailed description of pain and its location, since pain is a sign of disturbances

in the flow of qi. Observation of patient's posture, color of the skin, inspection of the color and coating of the tongue, and analysis of secretions of the mouth and nose for color and consistency may uncover deficiency or excess of qi. Palpation of temperature and tone of the tissues and an involved study of the radial pulse is also done. The patient interview should also include details of sleep, appetite, lifestyle, and psychological state.

In addition, the acupuncturist must consider of the cycles of the years, seasons, the change from night to day, and the monthly phases of the moon, all of which can affect the nature of the symptoms. The time and date of the patient's birth will in fact determine his or her energetic make-up.² The time of day during which a patient has his symptoms may aid in the diagnosis. In summary, diagnosis in TCM involves subjectively integrating a wide range of factors as a whole rather than objectively assessing each sign and symptom as separate and unrelated entities as is practiced in western medicine. Therefore, diagnosis is a greatly individualized holistic process.

Likewise, treatment is also very individualized. For a given disease or dysfunction, there is no standard treatment protocol. Although there are basic formulas and point prescriptions, treatment is adjusted to fit the individual patient. Thus, a traditional acupuncturist may see a dozen patients with low back pain and treat each one differently. Treatment involves the insertion of acupuncture needles into designated acupuncture points (acupoints), thus causing changes in the flow of qi through the channels. The acupuncturist manipulates the needles utilizing various techniques in order to restore a state of balance and in turn restore the patient's health. To achieve individuality of treatment, variations would include the use of different acupoints and/or

different needling techniques. In addition, the acupuncturist will modify treatment of a patient as the individual's clinical condition changes.

The acupuncture needle has changed over time. In ancient times, acupuncture needles were formed from stone or bone.² Today's needles are of filiform steel that is flexible, thus preventing breakage. The diameter of the needles varies from 0.2 to 0.6 millimeters and length varies from one to 10 centimeters.² The depth and angle of needle insertion varies, depending on the acupuncture point used and the patient's constitution.² The speed of insertion also varies according to the effect that is desired. When the needles have been placed appropriately, the patient shall experience the sensation referred to by TCM as *de qi* (teh chi). The exact sensation may vary slightly from patient to patient but is typically described as a sensation of numbness, accompanied by sensations of deep aching, heaviness, and/or tingling, but never pain. Absence of *de qi* sensation indicates failure to properly locate the acupuncture point. Following insertion, the needles are manipulated to achieve the desired effect. The techniques may involve lifting, thrusting, rotation, and/or vibration of the needles.² Once the needles have been properly inserted, they are left in place for 10 to 30 minutes.²

CHAPTER 3

TYPES OF ACUPUNCTURE

Traditional acupuncture usually refers to those styles of treatment based on the traditional Chinese medicine (TCM) method of diagnosis and treatment. However, many different styles of traditional acupuncture have arisen over the years, in China and throughout the rest of the world. Acupuncturists from different schools may differ in their prescription of acupuncture points (acupoints) and needling techniques for a particular patient. Nevertheless, the locations of the classical acupuncture points remain in agreement.

A differentiation must be made between the **traditional** acupuncturist and those practitioners in both the East and the West who practice “**classical**” acupuncture. Classical acupuncturists do not use the TCM based methods of diagnosis but instead use the methods of Western medicine to determine the disease or dysfunction. However, once they come up with a diagnosis, they will use its corresponding “formula” of classical acupuncture points. These classical point locations are those derived from TCM principles even though the practitioners may no longer subscribe to them. Other forms of acupuncture will not use the classical point locations but will insert needles into trigger points, tender areas, points in the same dermatome as the pain, etc. These are employed by many modern practitioners, who thus have little in common with traditional acupuncturists other than the use of needle insertion.⁵

In addition to the above variations of traditional acupuncture, there are other types of treatment which have evolved from the concepts of traditional acupuncture, many of them of recent derivation. Ear acupuncture involves the insertion of needles at points on the external ear. The belief is that the parts of the human body can be mapped out on the auricle, just as on the homunculus of the brain, and thus pain relief can be elicited through the stimulation of the corresponding points on the ear. Ear acupuncture points are used for acupuncture anesthesia during operations. Hand acupuncture and scalp acupuncture are both based on the same concept as ear acupuncture, with body regions represented on the hand and scalp, respectively.² Acupressure involves massage at acupuncture points, usually utilizing pads of the fingers or thumbs.

Electroacupuncture (EA), introduced in the 1950s,² is now used routinely in both clinical applications and in studies of physiological pathways of acupuncture analgesia. This technique involves the attachment of an electrical stimulator to needles that have been inserted into acupuncture points. Instead of manual manipulation of the needles to elicit de qi sensation, stimulation of the needles is provided by electric current. EA uses high intensity, low pulse frequency (number of stimuli per second, measured in hertz) electrical current. Intensities of five to 10 times threshold levels for muscle contraction (ie, 25-50 volts, 2.5-5 milliamperes at a pulse width of 0.1 milliseconds) are required.² Low frequency stimulation will cause individual muscle twitches, while high frequency (greater than 20 hertz) stimulation will not allow the muscle to relax, thus causing tetanic spastic contraction. The optimal pulse frequency to elicit de qi is 2-4 Hertz, which approximates the frequency used in manual needle stimulation of traditional acupuncture.² EA provides greater ease in controlling stimulus parameters and reduced

tissue damage⁷ compared to manual acupuncture. In addition, EA stimulation allows electric current to spread out from the needle for several millimeters, thus requiring less accurate needle placement than acupuncture with manual stimulation.² Although there is no conclusive evidence that the results obtained by EA and manual acupuncture are the same, the differences between the two appear to be at most quantitative. It is possible to stimulate a larger area with electric current. Therefore, it may not be incorrect to treat the results of manual acupuncture and EA as the same.⁸ There are other forms of electrical stimulation that may be referred to acupuncture because they involve stimulation of acupuncture points. However, instead of needles, electrodes (eg, with transcutaneous electrical nerve stimulation (TENS)) or a probe may be used.

Laser acupuncture is the irradiation of acupuncture points with laser light of low intensity, usually for the treatment of skin diseases and chronic pain conditions. Points either on the body or on the ear are irradiated for 10-30 seconds each per treatment session.²

As one can see, many of these forms of acupuncture show little resemblance to traditional acupuncture as described in TCM. In light of all the different forms of treatment that have been referred to as acupuncture, when discussing acupuncture one must be explicit in terms of type and method. Furthermore, conclusions made from one form of acupuncture may not validly be applied to other forms.

CHAPTER 4

PHYSIOLOGICAL PAIN MECHANISMS IN ACUPUNCTURE

There have been hundreds of published papers from western scientific literature which have uncovered the physiological pain mechanisms of acupuncture and electroacupuncture (EA), with most of these studies conducted on animal subjects.² The physical manipulation of the needles stimulates small diameter nerves which send impulses to the spinal cord. These impulses travel to the midbrain and pituitary and activate a number of neuroendocrine and hormonal changes, which cause the blockage of pain messages.² There are three major pain-modulating neurotransmitters: substance P, beta endorphin, and enkephalins. The increase in endogenous opioid level of the brain with acupuncture is caused by beta endorphin in the brain, and met-enkephalin and dynorphin in the spinal cord.⁸ By binding to opioid receptors, endorphins elicit pain relief.

To understand the mechanisms involved, let us first review the pathway of a pain stimulus. Nociceptors are high-threshold nerve endings in skin, and their stimulation is the first event in pain generation.¹⁰ When nociceptors are stimulated, ascending impulses are sent along small afferent nerve fibers (ie, A-delta and C fibers). The major ascending pathways are the spinothalamic and spinoreticular tracts, which involve both oligosynaptic and polysynaptic neurons. Stimulation of the oligosynaptic pathway results in sharply localized pain, while stimulation of the polysynaptic pathway leads to poorly

localized, dull aching or burning sensations.¹⁰ The message travels to the thalamus and is eventually sent to the cortex (most likely the somatosensory cortex).²

With acupuncture needle stimulation, a sensory receptor is activated, sending impulses to small diameter myelinated afferents (type II and III muscle afferent nerves or A-delta fibers)² and resulting in the elicitation of de qi sensation in the patient. De qi sensation indicates correct placement of the needle into the acupuncture point (acupoint) and is characterized by sensations of numbness, fullness, heaviness, and mild aching. Stimulation of the type II afferents are believed to signal the sensation of numbness, and type III, the sensations of fullness, heaviness, and mild aching.¹¹ These nerves synapse in the spinal cord onto the anterolateral tract (ALT), and from there the message travels to one or more of the following centers: the spinal cord, the midbrain, and the pituitary-hypothalamus complex.² Each center involves a different proposed mechanism of pain relief. When the spinal cord is stimulated, enkephalin and dynorphin are released, which cause presynaptic inhibition of the nociceptors of the pain transmission. This is probably due to reduction of calcium current inflow at the terminals of these nerve cells during the action potential, resulting in reduced release of the pain transmitter.²

Stimulation of the midbrain center is caused by impulses ascending the spinal cord in the ALT.² This excites the cells in the opioid-rich periaqueductal grey (PAG) region of the midbrain,² the most clearly understood mechanism of analgesia and, it appears, the most important. Impulses travel from the PAG to the nucleus raphe magnus and nucleus locus ceruleus causing the release of serotonin and norepinephrine, respectively. Descending in the dorsolateral tract are second-order neurons to opioid-secreting interneurons primarily in laminae I, II, and V of the dorsal horn. These

interneurons inhibit A-delta and C fibers either by presynaptic inhibition of the release of substance P (ie, the neurotransmitter of the first-order afferent neurons responsive to noxious stimuli) or by postsynaptic inhibition of second-order ascending neurons.

The mechanism involving activation of the pituitary-hypothalamic complex is not well understood. It is believed that the nucleus arcuatus of the hypothalamus may activate the raphe nucleus via beta-endorphin, causing the release of serotonin and norepinephrine onto the spinal cord cells as described above.² In addition, the hypothalamus may release beta-endorphin from the pituitary gland, thus elevating beta-endorphin levels in the cerebral spinal fluid (CSF).² However, the means of beta-endorphin reaching the brain has yet to be elicited.²

In theory, when needle insertion is in close proximity to the painful area, there is a utilization of all three mechanisms of pain relief at the spinal cord, midbrain and pituitary-hypothalamic centers. When needles are placed distally from the site of pain, they activate only the midbrain and pituitary-hypothalamic centers. This may explain why needle insertion at local segmental points gives more intense pain relief than distal nonsegmental needling. Typically, the acupuncturist will use both distal and local point locations during treatment.²

It is important to keep in mind that most of the research on the physiological bases of pain relief with acupuncture have been performed on animal subjects using EA. Whether these mechanisms can be applied to acupuncture with manual stimulation, and whether these mechanisms are even valid in humans remains debatable.

CHAPTER 5

METHODOLOGY OF PAST ACUPUNCTURE CLINICAL TRIALS

While research has provided possible physiological mechanisms for acupuncture analgesia, western standards of research demand significant results from clinical trials using human subjects. There have been several reviews of the clinical studies on acupuncture's analgesic efficacy in the recent past.¹²⁻¹⁵ The consensus has been that although results favor acupuncture, conclusive evidence is lacking. Methodological problems such as poorly defined entry criteria, poor design, small subject pools, inadequate outcome measures and statistical analysis, no clear definition of success or failure, lack of follow-up data, and sub-standard treatment have plagued many studies.^{5,15-17} In addition, many studies of acupuncture lack establishment of an appropriate placebo control, causing potential misinterpretation of clinical trial results.¹⁷ The rest of this chapter takes a closer look at the problems that have plagued studies in the past.

Design

Choosing the appropriate research study design when conducting clinical trials of acupuncture has proved difficult. While uncontrolled trials of acupuncture are prevalent in the literature, these trials can do nothing more than implicate acupuncture's efficacy. There is no way of knowing what effects are due to the natural course of the condition or due to the desired effect of treatment.⁵

A cross-over design is inappropriate due to the variable duration of acupuncture's analgesic effect and variable speed of response. In a cross-over study, one group of patients is treated with real acupuncture treatment while another group serves as a control or is given conventional treatment, and after a period of time, the groups switch treatment. Acupuncture analgesia can last for as short as a few hours to as long as a few years, even with the same treatment.²⁴ Meanwhile, response time of analgesia can range from immediate pain relief to slowly progressive analgesia.^{18,19} Therefore, a cross-over design cannot be considered a legitimate alternative for acupuncture studies.

A comparative-based design has been established as the most appropriate for studies of acupuncture analgesia. Most of the comparative studies can be placed into one of three categories according to the type of control group utilized: no treatment; an alternative treatment; or placebo.⁵

A no-treatment control group may give the clinician an idea of the natural course of the condition, but it fails to take into account the placebo effect of a physical treatment such as acupuncture.⁵ Patients have been shown to achieve pain relief just because they expected to have a reduction in pain. Therefore, a placebo control must be utilized to be sure that the results of the study are due to the specific effects of the experimental condition (ie, needle insertion) rather than non-specific (ie, placebo-related) factors.⁵

Comparing acupuncture to a conventional treatment, such as drugs or physical therapy, may allow comparison of side effects between the two treatments but fails to provide substantial proof of a treatment's specific effects.⁵ Often these conventional treatments [eg, conventional transcutaneous electrical nerve stimulation (TENS)] themselves have not been scientifically proven to provide pain relief.²⁰ Even when the

conventional therapy is a proven form of treatment, there is the likelihood that it will not have the same psychological impact as acupuncture. If this is the case, the patients will have different expectations of outcome. Expectations of outcome have been shown to affect the response to treatment.⁵ In other words, a conventional treatment may appear to be more effective than acupuncture in relieving pain, but the difference may be due to the fact that the subjects receiving acupuncture did not expect to gain pain relief, while those receiving the conventional treatment did expect to get better.

A placebo-controlled comparative design is the most appropriate for acupuncture studies. The use of a placebo control condition is well-established in drug evaluation research in order to show that improvement is caused by the specific effects of the true treatment rather than non-specific factors.⁵ Scientific evaluation of other treatments, including acupuncture, have followed suit in employing placebo controls to eliminate non-specific factors which may interfere with results.

Choice of placebo

The ideal placebo would be a bogus acupuncture treatment that simulates needle insertion but does not have any effect on the patient. However, such a placebo may not exist. Some studies have used placebo control where acupuncture needles are not inserted but are only rubbed or glued to the skin²¹ or poked with the needle or another object to simulate needle insertion. One would think that patients, even if never experiencing acupuncture before, would not find this to be a very credible treatment.⁵

Many studies in the past have used random needling, known as “sham” acupuncture,^{22,23} as the placebo control. In this technique, instead of using active acupuncture sites the acupuncturist will randomly insert acupuncture needles into sites

that are clearly off meridians and away from acupuncture points (acupoints).²⁰ However, the incorrect assumption with this is that simply inserting needles has no effect on pain. Diffuse noxious inhibitory control (DNIC) is a theoretical mechanism in which noxious stimulation of heterotopic body areas may cause analgesia in another part of the body, as opposed to the gate theory of pain modulation, which would explain pain relief in homosegmental body areas.¹⁵ This may explain why sham acupuncture may have a response rate (ie, percentage of patients experiencing subjective pain relief with treatment) of 40-50%, as opposed to 60% for real acupuncture,¹⁶ and placebo control, with a predicted 30% response rate.²⁴ Thus sham acupuncture cannot be considered a placebo. Trials which compare true acupuncture to sham acupuncture therefore provide information only about the role of point location.²⁵

Minimal acupuncture²⁶ is another acupuncture placebo. It involves needle insertion away from acupuncture points, as in sham acupuncture, but with only superficial needle penetration (ie, 1-2 millimeters) and only slight stimulation. Proponents believe that if minimal acupuncture has a therapeutic effect, it will be so small that it may still serve as a valid placebo, although it may be harder to elicit a significant difference between true treatment and control.¹⁷

Many researchers have used as placebo controls bogus forms of other physical treatment modalities, such as mock TENS. Mock TENS utilizes actual transcutaneous electrical nerve stimulator setup; the only difference is that no current passes between the electrodes. When utilizing mock TENS as placebo, the researchers may tell their patients that "they are receiving subliminal pulse therapy and that they will therefore not feel the

current.”¹⁷ Mock TENS has shown a placebo response rate of 30%^{17,24,27} similar to that expected from placebo medication.²⁷⁻²⁹

However, when choosing a placebo control such as mock TENS, one must take into account the possibility of different expectations of improvement between the control treatment and acupuncture. When comparing drug trials, where the experimental and control treatments are of the same form (ie, a pill), there is little concern for psychological factors.⁵ The drug and its placebo are indistinguishable by the patient, as well as the experimenter.¹² In fact, it is not common to assess non-specific factors in any treatment evaluation, except in psychotherapy research. However, in placebo-controlled trials of physical treatments such as acupuncture, one must be sure that the subjects view both actual and control treatments as equivalent in placebo power.¹⁷ There is then a possibility that any advantage shown by a true treatment may simply be due to its arousal of different expectations of improvement or other non-specific factors rather than the specific action of the needles.^{12,30} It is important to ensure that the specific treatment is not just functioning as a more effective placebo.¹²

Petrie and Hazleman,³¹ however, argue that mock TENS may be a valid placebo for controlled studies of acupuncture analgesia if strong visual and verbal suggestion are employed and assessment of patient expectancy of effectiveness is taken. Assessment of the patient’s expectations of treatment is a very important factor to monitor. The non-specific factors that may influence response to a treatment are too numerous to each be assessed. However, if a researcher were to assess just one of these non-specific factors, he could indirectly determine the strength of the patient’s expectations of improvement.⁹ One such non-specific factor is the patient’s perception of how credible a treatment is.

The basic assumption is: the more credible the patient perceives a treatment to be, the greater his expectations of improvement from that treatment. The assessment of credibility has proven to be a one of the best means of measuring the strength of the subject's expectations of improvement.^{9,17} Borkovec and Nau³² developed a treatment credibility rating method that has been utilized extensively in psychotherapy research and that lends itself well to assessing non-specific factors in controlled trials in other areas of research.¹²

The reliability and validity of using credibility assessment as a measure of the subject's expectations of improvement in acupuncture trials has been established.⁹ As a result, credibility assessment has been recommended by several experts in the field^{9,12,17} for use in placebo-controlled trials of acupuncture, including those trials using mock TENS or even minimal acupuncture as placebo. Although minimal acupuncture may be similar to true acupuncture in form, it may not conjure up equivalent expectations of improvement, especially since no de qi sensation is elicited with minimal acupuncture.

Single- versus double-blind trials

In a randomized placebo-controlled trial it would be ideal to have a double-blind methodology.⁵ A double-blind procedure requires both the patient and the practitioner to be blinded as to who is in the experimental group and who is in the control group. Obviously, if the patient were aware of which group he or she was in, then the placebo control would be useless. If the practitioner is not blinded to group assignment he may inadvertently convey his or her expectations to the patients, thus influencing the response.⁵ To ensure a double-blind trial, some studies have employed two different practitioners, one to perform the true treatment and one to perform the control condition.

In this situation, however, one may very well be comparing the persuasiveness and personality of one practitioner over another rather than comparing the effects of the experimental and control conditions.²⁴ The more charismatic practitioner may elicit greater confidence in his group of patients, and therefore that group would show a greater amount of improvement. A double-blind study with one practitioner performing both true and placebo treatments is difficult, if not impossible in acupuncture studies. Because the practitioner is performing an active treatment and not just giving a pill to the patient, he will be aware of whether he is performing a bogus treatment or true acupuncture. The lone exception would be a study with mock TENS as placebo, where the practitioner performs electrode set-up and treatment procedure but that a current is being passed through the apparatus when in actuality there is none.

Potential bias due to the single-blind nature of the study may be limited by keeping communication between the patient and practitioner to a minimum. In addition, credibility assessment has been suggested as a solution for this as well. It is necessary to assess credibility both before and after the treatment period.¹⁷ If the practitioner inadvertently “sells” the true acupuncture treatment over the placebo, it will be evident in the credibility assessment taken at the end of the treatment period. In such a case, the true group and the control group would have equal credibility assessments at pre-treatment screening, but the true group would have a higher expectation of outcome at the end of the treatment period.

Outcome measures

Adequate measures of treatment outcome have been lacking in many studies in the past. Although outcome measures will vary depending on the type of pain being

treated, there are several factors that are essential. All outcome measures, whether they be from subjective interview or from physical assessment, should be collected by an independent observer who is blinded to group assignment to avoid any bias in interpretation. Statistical analysis should also be conducted by a blinded individual.

Prior to start of treatment, pain data should be taken for a set period of time to establish a baseline measurement. During the treatment period, outcome measures that are taken at multiple times daily will give a better view of the actual response than if measures are taken once a week. Finally, long-term follow-up assessment (at least 6 months after treatment) is important, especially if the condition being treated is chronic in nature.⁵ Short-term pain relief is of little clinical value to chronic pain sufferers.

There should be a multidimensional assessment of pain, and both subjective and objective measures should be assessed.⁵ Subjective measures are easily biased by patient's perceptions and expectations. Objective measures, such as joint range of motion if a painful joint is being treated, will offer definitive proof of efficacy. Measures such as decreased medication intake and increases in activities of daily living will provide validation for subjective reports of pain relief.⁵ Many studies use global ratings of improvement (eg, much improved, slightly improved, etc.). However, such generalization may lead to loss of specific information about improvement.⁵ In addition, some studies have failed to display in their results comprehensive data and statistical analysis from which they draw their conclusions. Often appropriate statistical tests are not performed at all.

Other important considerations

There are several aspects derived from traditional acupuncture that pose problems for investigators. Traditional acupuncture requires individualized treatment as well as alterations in treatment over time as the patient's symptoms change. Acupoint locations and number of points, type and duration of needle manipulation, and duration of needle insertion will vary from patient to patient and from treatment to treatment. All these factors are at the acupuncturist's discretion. Restricting the variation of treatment procedures may reduce the effectiveness of acupuncture treatment.⁵ However, scientific research requires standardization in treatment procedures for the purpose of replication.⁵ A balance between variability of treatment and standardization must be achieved in order for the trial to be valid.

The investigator must specify the type and method of acupuncture used as the true treatment. With the term acupuncture encompassing such a wide range of procedures, there understandably is much confusion when analyzing research studies. Vincent⁹ believes that there may be a possibility that "one form of acupuncture will be effective with a given disorder whereas another may not, and that this may explain apparently discrepant findings" in research so far compiled. The number and frequency of treatments is also a factor that must be addressed. Studies that assess the efficacy of treatment consisting of just one session of acupuncture for each of its subjects likely will not achieve the full impact of which acupuncture may be capable.⁵ In such a case, acupuncture may incorrectly be characterized as ineffective. In light of these factors, it is essential that the investigator explicitly detail the parameters of the true treatment in his study. The method of diagnosis (traditional versus western), the specific acupoints used,

the frequency and duration of treatments, and whether de qi sensation was sought all should be addressed.⁵ The qualifications of the acupuncturist should also be reported. Experience and credibility of the acupuncturist will vary from study to study, and it is not unthinkable that a less qualified acupuncturist will not elicit the full benefits of acupuncture treatment.⁵

With the demand for higher quality research studies of acupuncture analgesia well established, has there been a recent influx of published trials with legitimate results? The following chapter is a literature review of the published clinical studies regarding acupuncture analgesia over the past decade to see if the latest studies have avoided drawbacks of past trials and thus provide a more definitive answer regarding acupuncture's efficacy.

CHAPTER 6

REVIEW OF THE LITERATURE

Methods

Vincent and Richardson¹² published the most comprehensive review of acupuncture trials for pain to date. They reviewed all acupuncture studies up to 1985, and concluded that in “most of the areas reviewed the usual call must be made for more and better studies before firm conclusions can be drawn”¹² regarding acupuncture analgesia. The present paper looked at all the published studies since Vincent and Richardson’s study to see if any new conclusions can be drawn regarding acupuncture’s effectiveness. Included in this review were clinical trials involving some form of reference group (ie, either a control or an existing treatment modality). Trials were not included if they were uncontrolled. Only trials involving traditional, classical, or trigger point acupuncture, or electroacupuncture (EA) using needles were included in this study. Origins of pain were musculo-skeletal or conditions traditionally seen in an outpatient physical therapy clinic (eg, migraine headache). A complete list of trials that were excluded is not presented. The types of pain populations covered in this literature review were: migraine headache,^{33,34} tension headache,³⁵⁻³⁷ facial pain,³⁸⁻⁴¹ neck pain,⁴² cervical osteoarthritis (OA),⁴³ tennis elbow pain,^{44,45} low back pain,^{46,47} knee OA,^{48,49} and fibromyalgia.⁵⁰ A brief synopsis of each of the 17 studies covered in this review is

presented in Table 1. The following is an analysis of these trials, with special attention paid to design and choice of control condition.

Results

Of all the studies, two^{47,48} had a control group which received no treatment. When conducting a study with a physical application such as acupuncture, one must eliminate non-specific factors. Without a valid control or credibility assessment there is no way of knowing if the results of the treatment are due to the specific effects of acupuncture or due to the placebo effect. Therefore little can be concluded from the results of either study regarding the efficacy of acupuncture.

A cross-over design was implemented in two studies^{36,43} but the results offer little information due to the study design. As has been noted previously, such studies are not appropriate with acupuncture due to acupuncture's varying response time and duration of response.

Acupuncture treatment was compared to conventional treatment without any placebo control condition in five of the studies reviewed.^{33,35,38-41} When comparing two different physical treatments there is the likelihood that the two treatments will elicit different connotations from the patients and therefore will conjure up different expectations of improvement. Credibility assessment, as mentioned in the previous chapter, is one of the only ways to eliminate this source of bias. However, these five studies all failed to conduct assessment of credibility, and so the results of these trials must be viewed with some skepticism.

Comparing acupuncture to physical therapy (PT) on patients with chronic tension headache, Carlsson et al³⁵ showed that the PT group had a significantly lower headache

Table 1.—Methodological Criteria for Controlled Clinical Trials of Acupuncture for Pain

Authors	Population	Study Design	Type of Acupuncture	Outcome Measures	Results
Hesse et al, 1994	77 patients with migraine HA	Group comparison: group A—n=38, AP and placebo tablets; group B—n=39, placebo AP and metoprolol (a beta blocker) 100 mg daily	True—trigger point dry needling for a few s, 6-8 treatments over 17-wk period, de qi not mentioned; placebo—skin touched superficially with blunt end of the needle	HA diary—frequency, severity, duration and global rating of HA, analgesic intake; investigator and statistician blinded from group assignment	Group A showed significantly greater improvement with regard to global rating of attacks compared to group B.
Vincent, 1989	30 patients with migraine HA	Controlled single-blind: true AP group—n=15; control group—n=15	True—classical, once a wk for 6 wk, de qi not mentioned; placebo—superficial needle insertion away from classical points	HA diary—(during treatment and for 2 wk at 4-mo and 1-y follow-ups) intensity, number of painfree d/wk, peak pain score each wk, analgesic intake; credibility assessment—taken at 2 nd and 5 th wk of treatment; blindness of examiner not mentioned	True group achieved significantly greater reduction in mean daily pain scores than control group: 43% to 14%, respectively; no significant difference during follow-ups; non-significant reduction in analgesic intake; credibility assessment confirms that both groups perceived their respective treatments as equally credible
Carlsson et al, 1990	62 female patients with tension HA	Group comparison (different practitioners for each group): AP group—n=31; PT group—n=31, 10-12 sessions performed over 2-3 months, treatment of massage, cryotherapy, TENS, relaxation techniques, strengthening and conditioning program	Classical point locations, 1 st treatment manual stimulation, afterwards EA (1-2Hz frequency) used, 4-10 treatments over 2-8 wk period, de qi elicited	HA intensity rating on 5-point scale; physical exam—tenderness to palpation at temporalis, corrugator, orbicularis, masseter, SCM, and trapezius, cervical spine ROM; 1 measurement period 4-9 wk after treatment; blindness of examiner not mentioned	HA intensity significantly lower in PT group compared with AP group; PT group significant reduction in tenderness in corrugator, orbicularis, and masseter muscles compared to AP group
Hansen and Hansen, 1985	18 patients with tension HA	Controlled cross-over trial: treatment divided into five 3-wk periods, each patient randomly assigned to either true (n=13) or placebo group (n=12) during 1 st treatment period, vice versa during the second, etc.	True—classical, two 3-wk periods, during each period patient treated 2 times per wk, de qi elicited; placebo—superficial needle insertion away from acupoints	daily pain diary; blindness of examiner not mentioned	True group significantly more pain-relieving than control group
Tavola et al, 1992	30 patients with tension HA	Controlled single-blind: true AP group—n=15; control group—n=15	True—traditional, 8 treatments over 8 weeks, de qi elicited; placebo—superficial needle insertion away from acupoints	pain intensity on 4-point scale, pain duration and frequency, analgesic intake, headache index; all measures taken after 4 and 8 wk of treatment, and at 1, 6 and 12 mo follow-ups; independent examiner blinded to group assignment	HA frequency, analgesic intake, and HA index significantly decreased over time in both groups; trend towards greater improvement in true group than placebo but no significant differences between the two

NOTE: HA = headache, AP = acupuncture, PT = physical therapy, TENS = transcutaneous electrical nerve stimulation, EA = electroacupuncture, SCM = sternocleidomastoid, and ROM = range of motion.

Table 1 (continued)

Authors	Population	Study Design	Type of Acupuncture	Outcome Measures	Results
Johansson et al, 1991	45 patients with facial muscular pain	Group comparison: AP group—n=15; occlusal splint therapy group—n=15, patients fitted with an occlusal splint; control group (no treatment)—n=15	Classical, 6 treatments, de qi elicited	Subjective—pain rating on 5-point scale and VAS, subjective improvement rating on 4-point scale; clinical exam—clinical dysfunction score composed of: tenderness to palpation of TMJ and masticatory muscles, TMJ sounds, mandibular movement, deviations of mandible during opening, and occlusal conditions; experimental groups were assessed 3 mo after treatment, control group assessed 2 mo after initial visit; independent observer blinded to group assignment	90% in AP group and 86% in splint group showed subjective improvement after treatment; significant improvement in all measures for both experimental groups but no significant differences between groups
List et al, 1992	110 patients with CMD	Group comparison: AP group—n=40; occlusal splint therapy group—n=40, treatment of occlusal splints worn at night for 7-8 wk; control group (no treatment)—n=30, after 3 mo control period, patients given stomatognathic treatment	Classical point locations, during first 2-3 treatments, manual stimulation used alone, during remaining treatments, both EA (2-3Hz frequency) and manual stimulation were combined, at least 6 treatments total over 6-8 wk, de qi elicited	Self-administered questionnaire—including toothache, HA, neck and shoulder pain), subjective improvement rating on 5-point scale, ADL scale; pain diary—pain intensity (VAS), frequency, analgesic intake; CDS (determined from ROM of mandible, function of TMJ, palpation of TMJ and masticatory muscles, and pain on movement of mandible); blindness of examiner not mentioned	AP group showed significant reduction in anamnestic index compared to other groups, 98% of AP group and 65% of splint group felt at least somewhat better after treatment; significant difference in ADL scale for AP group compared to other groups; in AP group, significant reduction found for all assessment variables except analgesic intake, whereas splint group significant reduction found only for pain intensity according to VAS and CDS; at 12 mo follow-up 57% of AP group and 68% of splint group remained clinically and subjectively better
Raustia et al, 1985	50 patient with TMJ dysfunction	Group comparison (different practitioner for each group): AP group—n=25; dental group—n=25, treatment of counseling, occlusal adjustment, muscular exercises for lower jaw, splint therapy, or a combination	Classical, 3 treatments over 1 mo, de qi not mentioned	Clinical exam—maximal mouth opening measurement, clinical dysfunction index composed of: mandibular ROM, TMJ function and pain, muscle pain, and pain on movement of mandible; subjective improvement rating on 4-point scale; all measures taken at wk 1 of treatment and 3 mo after treatment; dentist who did dental therapy also did exam and evaluation for both groups	No significant difference in outcome measures between 2 groups although subjective assessment appeared to favor dental treatment at both observation periods

NOTE: AP = acupuncture, VAS = visual analog scale, TMJ = temporomandibular joint, CMD = craniomandibular disorder, EA = electroacupuncture, HA = headache, ADL = activities of daily living, CDS = clinical dysfunction score, ROM = range of motion, and TENS = transcutaneous electrical nerve stimulation.

Table 1 (continued)

Authors	Population	Study Design	Type of Acupuncture	Outcome Measures	Results
Petrie and Hazleman, 1986	25 patients with neck pain	Controlled single-blind: true AP group—n=13; control group (mock TENS)—n=12	Classical, 2 times per wk for 4 wk, de qi elicited	Daily pain diary—pain intensity (VAS), disability (VAS), analgesic intake; questionnaire—pain descriptor word score (taken at end of treatment and at 1-mo follow-up); physical exam—cervical ROM (taken at end of treatment and at follow-up); subjective pain intensity on 7-point scale (taken at end of treatment); examiner blinded to group assignment	No significant difference in any outcome measure, although trend toward improvement with AP group, especially at follow-up; response rate: 45% for AP, 30% for placebo
Thomas et al, 1991	44 patients with cervical OA	Group comparison cross-over: all patients treated once with all 4 of the following in randomized order with 2-3 wk between each treatment—diazepam 5 mg orally, placebo diazepam, AP, and placebo AP	True—classical, 1 session, de qi elicited; placebo—needles inserted superficially	Pain intensity (VAS) and pain unpleasantness (VAS) 2 h after treatment; blindness of examiner not mentioned	True AP group showed significant improvement in both outcome measures but not significantly better than diazepam or placebo AP.
Haker and Lundeberg, 1990	82 patients with tennis elbow pain	Controlled single-blind: true AP group—n=44; control group—n=38	True—classical, 2-3 times per wk, 10 treatments total, de qi elicited; placebo—superficial needle insertion at same acupoints	Physical exam—pain threshold on 5-point scale during following tests: palpation of lateral epicondyle, resisted wrist extension, finger extension, passive stretch of extensor muscles, isometric pronation and supination, grip strength, lifting test with 1, 2, 3, and 4 kg; measures taken at end of 10 th treatment, and at 3 and 12 mo follow-ups; examiner blinded to group assignment	After 10 treatments, pain threshold on gripping had significantly increased in true group compared to placebo group ^a ; significantly fewer patients in true group had pain when lifting 3 kg compared to placebo group ^a ; significant difference in subjective pain rating between groups ^b (50% in true group reported excellent or good results, compared to 21% in placebo group); no significant difference on any measures during follow-ups
Molsberger and Hille, 1994	48 patients with tennis elbow pain	Controlled single-blind: true AP group—n=24; control group—n=24	True—classical, 1 treatment, de qi elicited; placebo—pencil-like probe simulating needle insertion	Physical exam (1 time, after treatment)—pain intensity rated on 11-point scale with respect to pressure, load, movements of forearm; independent unbiased examiner	79% of true group reported at least 50% pain relief compared to 25% for placebo group (significant difference); average duration of pain relief in true group 20.2 h compared to 1.4 h in placebo group
Lehmann et al, 1986	53 patients with LBP	Group comparison: EA group—n=17; true TENS group—n=18; mock TENS group—n=18 (both TENS groups treated by a physical therapist blind to group assignment; EA performed by an acupuncturist)	True—EA, 2 times per wk for 3 wk, de qi not mentioned	Subjective—pain (VAS), disability rating on 5-point scale, ADL score (15 items); physical exam—trunk strength, spine ROM; physician's subjective—pain intensity rated on 10 point scale, impairment rating on 5-point scale; all outcome measures taken at end of treatment period and at 6 mo follow-up; blindness of examiner not mentioned	No significant difference between treatment groups; EA group consistently demonstrated greater improvement on outcome measures than the other groups

NOTE: AP = acupuncture, TENS = transcutaneous electrical nerve stimulation, VAS = visual analog scale, ROM = range of motion, OA = osteoarthritis, LBP = low back pain, EA = electroacupuncture, and ADL = activities of daily living.

^a $p < 0.05$.

^b $p < 0.01$.

Table 1 (continued)

Authors	Population	Study Design	Type of Acupuncture	Outcome Measures	Results
Thomas and Lundberg, 1994	40 patients with LBP	Group comparison: AP (manual stimulation (MS)) group—n=7; EA (low frequency (LF)) group—n=9; EA (high frequency (HF)) group—n=11; control group (no treatment)—n=10	MS—classical; LF—frequency of 2Hz, classical points; HF—frequency of 80Hz, classical points (all three treatment groups treated 2 times per wk for an average of 7 treatments)	Subjective—ADL score, pain descriptor word score, subjective improvement rating on 3-point scale; physical exam—ROM of SLR and of trunk lateral flexion, extension and forward flexion; all measures taken after 6 treatments and at 6 mo follow-up	After 6 wk all 3 experimental groups showed significant improvement on all measures except ADL score; at 6 mo follow-up LF group continued to have significant improvement but MS and HF groups did not
Christensen et al, 1992	29 patients with knee OA (total of 42 OA knees)	Group comparison: short-term study—group A treated with AP for 3 wk while group B served as no-treatment control; after 9 wk group B treated with AP also for 3 wk; long-term study—17 patients (26 knees) continued with AP treatments once a mo, total study period: 49 wk	Classical, 2 times per wk for three wk, de qi elicited	Clinical exam (taken 5 times during short-term study and 2 times during long-term study)—time taken to walk 50 m, time taken to climb 20 steps, knee function scale (ROM, walking distance, muscle strength, pain at rest and with exercise), analgesic intake; pain intensity—VAS (taken 9 times during short-term study and 10 times during long-term study); examiner blinded to group assignment	Group A showed significant reduction in pain, analgesic consumption and most objective measures compared to group B during control period; during period of combined treatment of both A and B, there was an 80% objective improvement and a significant increase in knee ROM
Takeda and Wessel, 1994	40 patients with knee OA	Controlled single-blind: true group—n=20; control group—n=20	True—classical, 3 treatments per wk for 3 wk, de qi elicited; placebo—superficial needle insertion 1 in from acupoints	Pain descriptor word score, pain intensity (VAS), stiffness and difficulty rating (VAS), pain threshold at 4 sites at the knee measured with a pain threshold meter; outcome measures taken after 3 wk of treatment and at 4-wk follow-up; examiner blinded to group assignment	Both groups showed significant reduction in pain, stiffness and physical disability; trend towards greater improvement in true group than placebo, but no significant difference between groups
Deluze et al, 1992	70 patients with fibromyalgia	Controlled single-blind: true group—n=36; control group—n=34	True—EA at classical points, frequency of 1-99Hz (continuous scanning), 6 sessions over 3 wk, de qi elicited; placebo—EA with superficial needle insertion away from acupoints with similar but weaker current	Pain threshold using a pressure gauge, analgesic intake, regional pain score, pain intensity (VAS), sleep quality, morning stiffness, patient's and evaluating physician's overall subjective assessment on 10-point scale; outcome measures taken after treatment period; examiner blinded to group assignment	Significant improvement in true group compared to control group in pain intensity (VAS), ^a morning stiffness, ^a patient's assessment, ^a physician's assessment, ^b and pain threshold ^a ; pain threshold improved by 70% in true group compared to 4% in control group.

NOTE: LBP = low back pain, AP = acupuncture, EA = electroacupuncture, ADL = activities of daily living, ROM = range of motion, SLR = straight leg raise, OA = osteoarthritis, and VAS = visual analog scale.

^a p < 0.05.

^b p < 0.01.

intensity and analgesic intake than the acupuncture group, and the PT group also was significantly better in terms of muscle tenderness reduction in some of the facial muscles tested (see Table 1). However, there are so many flaws in this study the results are questionable at best. First of all, PT and acupuncture were not done by the same clinician, leading to a potential source of bias. When experimental groups are run by different clinicians, one may very well be comparing the charisma and persuasiveness of one clinician over another rather than comparing the effects of the experimental and control conditions.²⁴ Such was indeed the case in the Carlsson study. In fact, the authors admit to bias in at least one outcome measure, analgesic intake, stating that it was “probable” that the physical therapist was “more anxious and energetic than the acupuncturists in persuading the patients to reduce their intake of analgesics.”³⁵ Furthermore, there was a disproportionate amount of PT treatments compared to acupuncture treatments. Patients in the PT group received 10-12 treatment sessions over two to three months, with 30-45 minutes of individual instruction for each session. On the other hand, only four to five acupuncture treatments were given to all the acupuncture group members, over a period of two to four weeks. Only if patients received “clear pain relief” were they given an additional four to five treatments. The authors made no mention as to how many patients received additional treatments.

Hesse et al³³ conducted a study of 77 chronic migraine headache patients, comparing the effects of trigger point acupuncture to that of a beta blocker (metoprolol) and a placebo pill. Group A was treated with trigger point acupuncture and placebo pills; Group B was given metoprolol and were touched superficially at trigger points with the blunt end of the needle. This choice of placebo acupuncture was inadequate, as it is hard

to believe that being touched with the blunt end of a needle would be perceived as a legitimate treatment by all members of group B. The results, however, showed that group A had significantly greater improvement with regard to global rating of headache attacks compared to group B. Of the studies covered in this review, this study is the only one to use trigger point acupuncture as its experimental condition and also one of the few studies not to seek de qi sensation during needling. The needles were left in the skin only for a few seconds and then removed, while in the other studies, needle insertion lasted at least ten minutes per session. The lack of prolonged needle stimulation and the absence of de qi leave doubts as to whether this form of acupuncture is equivalent to traditional or classical acupuncture in terms of efficacy.

Raustia et al⁴¹ compared the effects of acupuncture and standard stomatognathic treatment (occlusal splint therapy, counseling , and/or lower jaw muscle exercises) on 50 patients with temporomandibular joint (TMJ) dysfunction. Occlusal splint therapy involves wearing an acrylic resin stabilization splint worn in the maxillary arch to adjust occlusion of the mouth.³⁹ The results showed no significant difference in any of the outcome measures between the two groups.

Johansson et al³⁸ compared the effect of acupuncture and occlusal splint therapy on patients with chronic headache and/or facial pain of muscular origin. The subjects were divided into three groups, each with 15 members: one group was treated with acupuncture, another with occlusal splints, and a third was a non-treatment control group. This study showed very promising results in favor of acupuncture, with a response rate (percentage of patients experiencing subjective pain relief) of 90% for acupuncture and 86% for occlusal therapy. Placebo response rates in general have been shown to vary

between 1% and 69%,⁵¹ therefore the subjective results in this study cannot be attributed to the placebo effect. Outcome measures were taken just twice, once pre-treatment and once three months post-treatment. Inadequate baseline data and the paucity of outcome recordings allow for the possibility that the results were due to chance. In addition, lack of between-session data collection leads to a lack of insight into the day-to-day effect of the treatment. Furthermore, no long-term data were taken to surmise the treatment's prolonged effects.

The third clinical trial to compare acupuncture to occlusal splint therapy was conducted by List et al.³⁹ They compared traditional acupuncture with splint therapy and a no-treatment control on the 110 patients with craniomandibular disorders (CMD). The results show that the acupuncture group had significant reduction in subjective evaluation, ADL-scale, pain intensity (VAS), frequency of pain and clinical dysfunction score (CDS). The only outcome measure not significantly improved was analgesic consumption (see Table 1 for more details on assessment measures). As for occlusal splint therapy, the results showed significant results in VAS pain intensity and CDS. Ninety-eight percent of the patients in the acupuncture group showed subjective improvement, compared to 65% of the splint therapy group. Outcome evaluations were done only pre- and post-treatment. Two of the authors of this study, List and Helkimo, did perform a follow-up study⁴⁰ of the original subjects 12 months after the treatment period. Fifty-seven percent of the acupuncture patients and 68% of the occlusal splint patients showed subjective and clinical improvement at this follow-up (a non-significant difference between groups).

The studies by Johansson and List et al show great promise for acupuncture's efficacy in treatment of facial pain, including CMD. However, placebo controlled studies to completely rule out non-specific effects are needed to convince the skeptics. The remaining studies in this review did compare true acupuncture treatment to some form of placebo control. One study⁴⁵ used a pencil-like probe to simulate the sensation of a needle being inserted. It is hard to imagine that all the members of the control group would believe this to be a credible treatment. There was no form of credibility assessment to prove otherwise, and so this form of placebo remains invalid. The rest of the studies employed more legitimate forms of placebo control.

Two treatments used mock transcutaneous electrical nerve stimulation (mock TENS) as placebo.^{42,46} Petrie and Hazleman⁴² used a chronic neck pain population for its study. Results showed a response rate of 45% for acupuncture and 30% for mock TENS, a difference that is not significant. However, the number of subjects was extremely low (25), thus leading to the possibility of type II error, (ie, acupuncture has a significant effect but it was not detected). Despite the probability of different expectations of outcome when comparing two different types of treatment, in this case acupuncture versus TENS, credibility assessment was not performed. Prior treatment with TENS was not mentioned as an exclusion criterion in this study. A person who had received TENS treatment before would most likely appreciate the absence of current with mock TENS, and therefore would likely have decreased expectations of outcome. In addition, the clinician, who was not blinded to group assignment, may have inadvertently influenced the patients with his own expectations.

EA was compared to both mock TENS and regular TENS on a group of 53 chronic low back pain patients by Lehmann et al.⁴⁶ The EA group consistently showed greater improvement in the outcome measures (see Table 1) than both mock TENS and true TENS groups, but the differences did not reach significance. Although the practitioner who performed both mock and true TENS groups was blinded to group assignment, EA was performed by a different practitioner, and again credibility was not assessed. Furthermore, no mention was made whether those physicians assessing the treatment outcome measures were blinded from the treatment groups. Outcome data recording was done only three times: prior to treatment, at the end of the treatment period, and at six-month follow-up, resulting in unsatisfactory baseline measurements and inadequate frequency of data recording.

Vincent,³⁴ Tavola et al,³⁷ and Takeda and Wessel⁴⁹ all conducted controlled, single-blind studies using as a placebo control minimal acupuncture (ie, superficial insertion of needles away from acupuncture points (acupoints)).¹⁷ Vincent's study compared classical acupuncture to minimal acupuncture on 30 migraine headache sufferers. This was the only study in this review which performed a credibility assessment of the subjects. The results showed that both had equivalent ratings of credibility, thus eliminating the possibility of potential bias between the two groups. There was a significant reduction in weekly pain scores in the true experimental group of 43% compared to only 14% in the sham group (no p value given). However, several flaws were present. Blindness of the investigator who collected the outcome assessment data and the statistician was not mentioned, thus exposing a potential source of bias. Follow-up assessments at four and 12 months after treatment showed significant long-

term difference between groups in any outcome measure. Finally, the low number of subjects led to the possibility of type I error, in which case acupuncture in reality does not have an effect, contrary to the published results.

Comparing acupuncture to minimal acupuncture on 30 tension-type headache sufferers, Tavola's was unique in that it was the only clinical trial reviewed to use traditional acupuncture in terms of its diagnostic and therapeutic approach. The acupuncturist chose point locations according to traditional Chinese medicine (TCM) diagnosis for each individual (six to 10 points) and was allowed to alter points from session to session. Although headache frequency, headache index, and analgesic intake decreased over time in both groups, and there was a tendency for the true acupuncture group to show a greater response, no significant difference was reached between groups in any outcome measure (see Table 1). Long-term follow-up did not reveal any significant changes in the results. The small sample size of this study leaves open the possibility that acupuncture does indeed have an analgesic effect but it was not detected (ie, type II error).

Takeda and Wessel compared classical acupuncture to minimal acupuncture on 40 patients with OA of the knees. There were no significant differences between the two groups despite a trend toward greater response in the true acupuncture group. No long-term follow-up was performed. The subjects were not a proper representation of a normal pain population, since all of them were volunteers. As volunteers, they would likely have a more favorable opinion of the acupuncture than the general population, and so their expectations of outcome would probably be higher than normal.

A placebo control similar to minimal acupuncture but with the points in the same location as the true acupoints was utilized by Haker and Lundeberg⁴⁴ in a study of 82 patients with tennis elbow pain. One would expect that significant results would be more difficult with this form of placebo (ie, needle insertion at acupoints) as opposed to placebo needling away from acupoints. However, significant results were indeed attained in this study. Hand grip pain threshold had significantly increased in the true acupuncture group compared to placebo ($p < 0.05$), and significantly fewer patients in the true group had pain when lifting the three-kilogram weight ($p < 0.05$). Table 1 lists all outcome measures taken. There was a significant difference in subjective pain rating between groups ($p < 0.01$). Fifty percent in the true group had good to excellent results, compared to 21% in the placebo group. Long-term follow-up was performed, but no significant difference was found. True and placebo acupuncture both were performed by one of the authors, who may have projected bias on the patients, but, again, no credibility assessment was done. It was not mentioned whether any patients that had received acupuncture treatments in the past were excluded. Since the control group was treated with placebo acupuncture that did not elicit de qi sensation, members of this group who might have had previously received acupuncture treatments would have noticed the absence of de qi and probably would not have had the same expectations of improvement as those in the experimental group. Furthermore, baseline data was accumulated at just one testing period prior to treatment.

Deluze et al⁵⁰ compared the effects of EA and placebo on fibromyalgia patients. The placebo control could best be described as an EA version of minimal acupuncture. The needles were placed about 20 millimeters away from the acupoints used in the true

acupuncture treatment and were inserted only three to four millimeters deep (versus 10-25 millimeters in the experimental group). Furthermore, the acupoints were stimulated with a weaker current than the experimental group. The experimental group showed significant improvement over time in seven of eight outcome measures (see Table 1) after EA treatment, whereas the control subjects showed no significant improvement in any of the eight parameters. When compared to the control group, the experimental group showed significantly better results in pain threshold using a pressure gauge, pain intensity, morning stiffness, and patients' and physician's overall subjective assessment (see Table 1 for p values). Pain threshold, described by the authors as the "main parameter," showed improvement of 70% in the experimental group as compared to 4% improvement by the control group. Like most of the studies in this review, this trial lacked adequate baseline recordings, infrequent outcome testing (ie, one time post-treatment), and no long-term follow-up.

CHAPTER 7

CONCLUSION

All of the studies reviewed in this paper continue to contain at least a few of the same methodological mistakes that have plagued acupuncture research in the past.¹²⁻¹⁵ Those studies using cross-over design, group comparison to a different physical treatment or a no-treatment control, or employing an inadequate form of placebo acupuncture have not and will not convince the western medical establishment regardless of the results. Two³⁸⁻⁴⁰ of the three clinical trials comparing acupuncture to dental therapy on craniomandibular disorders (CMD) showed positive results that warrant further research utilizing placebo control. There is nothing more to be concluded from these studies that lack placebo control that has not already been determined in the past.

Seven^{34,37,42,44,46,49,50} of the 17 studies presented here had adequate placebo controls, and out of the seven, three^{34,44,50} showed significant differences in favor of acupuncture in at least one outcome assessment measure. The seven controlled studies in general successfully described the type of acupuncture and diagnosis used, the specific number and location of acupuncture points (acupoints), frequency and duration of treatment, and successfully elicited de qi sensation. These studies also had extensive multidimensional measures of pain, had adequate statistical analysis, and (with the exception of Vincent³⁴) blinded the examiner and statistician to group assignment.

While these placebo-controlled studies were generally of good quality, all contained at least a few flaws that leave their results open to criticism. Inadequate baseline testing, infrequency of outcome measure testing, lack of long-term follow-up testing, and small subject pools were common problems. The most glaring weakness was the absence of credibility assessment, which is required to eliminate differences in outcome expectations between the experimental and control groups. Despite the demand for proper credibility assessment in the literature^{9,12,17} in the past, as mentioned in the previous chapter, it is disappointing to see that only one of the studies in this literature review³⁴ performed credibility assessment on its subjects.

Acupuncture has been used to describe a wide array of procedures, many of which have little resemblance to traditional acupuncture, upon which all are based. The assumption that all forms of acupuncture are equally effective in the treatment of chronic pain conditions is unlikely and may explain why research in the past has turned up inconsistent findings.⁹ This study attempted to narrow its inclusion criteria in order to avoid this potential problem. Classical acupuncture or electroacupuncture (EA) using classical point locations were employed in all but two of the trials. The lone variants were Tavola's study,³⁷ which employed traditional acupuncture, and Hesse's study,³³ which used trigger point dry needling. Whether traditional and trigger point acupuncture are equal to classical acupuncture in effectiveness is also open to debate. In addition, the assumption that EA and acupuncture with manual stimulation are equivalent has never been proven⁸. A large number of well-designed single-blind placebo-controlled studies of acupuncture achieving significant results are necessary before one can attempt to address these assumptions.

Although only three^{34,44,50} of the seven placebo-controlled studies in this review attained significant results, all seven showed greater improvement in the experimental group versus the placebo group. This suggests the possibility that acupuncture may indeed have an analgesic effect, but that this effect may be only slightly greater than the placebo effect. As a result, acupuncture fails to consistently achieve statistical significance. With the use of minimal acupuncture as placebo, significant differences will be even more difficult to achieve, due to the needle stimulation involved (no matter how slight) and the effect of diffuse noxious inhibitory control (DNIC) caused by needle insertion.¹⁷ Nevertheless, an enhanced placebo effect cannot be ruled out as the cause for subjective improvement in all seven studies because of their methodological flaws and/or lack of credibility assessment. lack of credibility assessment.

While in general the studies in this review have shown limited improvement upon the mistakes of past studies, acupuncture research has not produced more conclusive evidence over the past ten years. Until studies are performed that are void of any methodological flaws, properly assess credibility, and consistently produce significant results in favor of acupuncture analgesia, the nation's medical establishment will refuse to accept acupuncture as a legitimate pain relief treatment.

Nevertheless, acupuncture use has continued to grow in the physical therapy (PT) profession throughout the world. In the United Kingdom (UK), for example, there is an acupuncture clinical interest group for physical therapists, the Acupuncture Association of Chartered Physiotherapists (AACP).⁶ It was formed in 1984, and as of 1991 had a membership of over 270.⁶ A recently conducted questionnaire study⁶ showed that 16% of these members had a background in traditional acupuncture, 29% in Western and 58%

with a background of both. Training ranged from two to 30 or more days. These practitioners had practiced acupuncture for an average of 3.9 years and treated 25% of their patients with acupuncture. Forty-seven percent used acupuncture for effects beyond the scope of pain relief. When asked to rate the efficacy of acupuncture for painful conditions, the respondents gave headache, migraine and neck pain almost total support, while low back, other spinal, shoulder and knee pain all were given strong but not complete support. Of course, these treatments were confounded by concurrent use of other physical therapy modalities. The majority of the practitioners did not practice the less accepted aspects of TCM such as pulse and tongue diagnosis. When selecting acupuncture points, 93% of the respondents said they used meridians "often" or "always," while 67% said they used tender points "often" or "always."

Despite the United States medical establishment's resistance to accept acupuncture as a legitimate means of pain relief, acupuncture use continues to grow in the PT profession here. However, the medical establishment has historically been slow to accept treatments which at the time were viewed as bogus but now are widely used and accepted (eg, TENS). Nevertheless, acupuncture should never replace conventional PT treatment when treating patients with chronic pain. In the study by Lehmann,⁴⁶ which was covered in the literature review, all the subjects took part in a comprehensive multidisciplinary educational program and a twice daily exercise program in addition to their respective electrotherapy program (EA, true transcutaneous electrical nerve stimulation (TENS), or mock TENS). The patients were asked at the conclusion of treatment and at follow-up (six months) to rate the contributions that education, exercise and electrotherapy components each played in the overall rehabilitation program. The

majority of patients, regardless of treatment group assignment, rated the educational component of the rehabilitation program the most beneficial and the electrotherapy portion the least beneficial.

Unless future clinical research attains conclusive scientific evidence supporting its analgesic effectiveness, acupuncture should serve as an alternative for chronic pain patients who have failed to respond to other conventional means of pain relief. Furthermore, physical therapists without extensive knowledge, training, and experience in acupuncture should refer patients to highly qualified experts in the field until guidelines are established determining the minimum amount of training required for competency.

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